

CLAIMS

1. A process for purifying a non-ionic solvent comprising the steps of:
  - (a) forming a solution of said solvent in alcohol and water, with or without aid of heating;
  - 5 (b) loading the solution on to a chromatography column packed with reverse phase silica
  - (c) running the chromatography column using de-ionized water as the mobile phase to purify the solvent;
  - (d) running the chromatography column using an eluent recovering the purified solvent; and
  - 10 (e) evaporating the residual water and the eluent.
2. The process according to claim 1 wherein the solvent is polyethoxylated castor oil or polyoxyl-35-castor oil.
3. The process according to claim 1 wherein the solvent is Cremophor EL or Cremophor ELP.
4. The process according to claim 1 wherein the alcohol is selected from the group consisting of methanol, ethanol, butanol or isopropanol.
5. The process according to claim 1 wherein the alcohol is ethanol.
6. The process according to claim 1 wherein the eluent is selected from the group 20 consisting of methanol, ethanol, isopropyl alcohol, acetone, acetonitrile and tetrahydrofuran.
7. The process according to claim 1 wherein the eluent is acetone.
8. The process according to claim 1 wherein the de-ionized water is HPLC grade.
9. The process according to claim 1 wherein in step (a) said solution is a 25 solution of polyethoxylated castor oil, alcohol and water.
10. The process according to claim 1 wherein said step of forming said solution comprises mixing about polyethoxylated castor oil, dehydrated ethanol and de-ionized water in a ratio of 10:1:33 w/v/v with or without the aid of heat.
11. The process according to claim 1 wherein said step of forming said solution comprises mixing about 300 gm of polyethoxylated castor oil, 30 gm of dehydrated ethanol 30 and one litre of HPLC grade non ionic water with or without the aid of heat.
12. The process according to claim 1 wherein said solvent is polyethoxylated

castor oil and the step the chromatography column comprises a column of 15 x 30 cms packed with reverse phase silica of C-8 or C-18 type having a particle size of 30 - 60  $\mu$ .

13. The process according to claim 1 wherein the step of running the chromatograph to purify the solvent comprises the use of de-ionized water as the mobile phase for 1 to 50 minutes.

14. The process according to claim 13 wherein the de-ionized water is HPLC grade.

15. The process according to claim 1 wherein the aqueous fractions are discarded.

16. A composition comprising combining the purified non-ionic solvent prepared according to the process of claim 1 and paclitaxel.

17. The composition according to claim 16 wherein the percent by weight of degradation products of paclitaxel after being stored at 50°C for 10 days is less than or equal to 0.3% wherein said degradation products are Baccatin III, Ethyl ester side chain of Paclitaxel, 10-Deacetyl paclitaxel, 10-Deacetyl 7-epipaclitaxel and 7-epipaclitaxel.

18. A process for purifying a polyoxyl 35 castor oil solution said solution comprising polyoxyl 35 castor oil, water and an alcohol said process comprising loading the solution on to a chromatography column packed with reverse phase silica and running the chromatograph using de-ionized water as the mobile phase followed by eluting the purified polyoxyl 35 castor oil with methanol, ethanol or acetone evaporating the residual alcohol, water and methanol, ethanol or acetone to obtain purified polyoxyl 35 castor oil adapted to produce, when combined with paclitaxel, a pharmaceutical composition not showing more than 0.3% degradation products of paclitaxel identified as Baccatin III, Ethyl ester side chain of Paclitaxel, 10-Deacetyl paclitaxel, 10-Deacetyl 7-epipaclitaxel and 7-epipaclitaxel, after being stored at 50°C for 10 days.

19. A process for purifying a polyoxyl 35 castor oil solution said solution comprising polyoxyl 35 castor oil, water and an alcohol said process comprising loading the solution on to a chromatography column packed with reverse phase silica of C-8 or C-18 type having a particle size of 30 - 60 $\mu$  and running the chromatograph using de-ionized water (HPLC grade as the mobile phase followed by eluting the purified polyoxyl 35 castor oil with methanol, ethanol or acetone, evaporating the residual alcohol, water and methanol, ethanol or acetone to obtain purified polyoxyl 35 castor oil adapted to produce, when combined with

paclitaxel, a pharmaceutical composition not showing more than 0.3% degradation products of paclitaxel identified as Baccatin III, Ethyl ester side chain of Paclitaxel, 10-Deacetyl paclitaxel, 10-Deacetyl 7-epipaclitaxel and 7-epipaclitaxel, after being stored at 50°C for 10 days.

- 5      20.        The process according to claim 19 wherein the eluent is acetone.
21.        A pharmaceutical composition comprising a solvent containing a solvent purified according to the process of any one of claims 1 to 15 wherein the solvent is a polyethoxylated castor oil and a pharmaceutical agent.
22.        The composition according to claim 21 wherein the pharmaceutical agent is  
10      an antineoplastic agent.
23.        The composition according to claim 22 wherein the pharmaceutical agent is paclitaxel.
24.        The composition of claim 21 wherein said solvent further comprises an alcohol.
- 15      25.        A stabilized pharmaceutical composition comprising a solvent containing a purified polyethoxylated castor oil according to claim 19 and paclitaxel, said composition showing not more than 0.3% degradation products of paclitaxel identified as Baccatin III, Ethyl ester side chain of Paclitaxel, 10-Deacetyl paclitaxel, 10-Deacetyl 7-epipaclitaxel and 7-epipaclitaxel, after being stored at 50°C for 10 days.